MEMORANDUM

TO: Members, Advisory Committee for Pharmaceutical Science

FROM: Helen Winkle
Acting Director, Office of Pharmaceutical Science

Date: 19 June 2001

RE: 19 - 20 July 2001 Meetings of the Advisory Committee for Pharmaceutical Science

Dear ACPS Members,

We have planned an ambitious program for the July 2001 meeting of the ACPS with many exciting topics. We look to you to help us set the direction for our regulatory processes and provide additional information for our policy-making activities. We appreciate your participation and look forward to your contributions to the discussions.

The Orally Inhaled and Nasal Drug Products (OINDP) Subcommittee will meet on July 17, 2001 prior to the main committee meeting. The results/recommendations from the OINDP meeting will be discussed on July 19, 2001. We have also planned a full-day orientation on July 18, 2001 to help advisory committee members better understand how OPS fits into the drug review process. This will enable you to hear more about specific OPS programs and give you an opportunity to meet some of the OPS employees.

Attached are articles that were selected by the speakers as background information to prepare you for the topics they will present. We understand the burden of this reading but feel it is a worthwhile exercise. This reading will prepare you for the discussions and enable you to fully participate and provide meaningful recommendations. Below is a brief outline of the topics that are scheduled for presentation. For some topics there are specific questions that you will be asked to address and for other topics we have planned a more general discussion. Again, we are anticipating rigorous scientific discussions and look forward to your participation.

July 19 Sessions

Orally Inhaled and Nasal Drug Products Subcommittee

The views of OINDP subcommittee on the two specific questions listed below will be presented to ACPS for consideration and subsequent recommendations

- Does the subcommittee believe that a placebo-controlled traditional two-week rhinitis study conducted at the lowest active dose is sufficient to confirm equivalent local delivery of suspension formulation nasal sprays and nasal aerosols for allergic rhinitis?

- Does the subcommittee believe that a placebo-controlled park study or an EEU study conducted at the lowest active dose is an acceptable option to confirm equivalent local delivery of suspension formulation nasal sprays and nasal aerosols for allergic rhinitis?

Non-Clinical Studies Subcommittee Update

A Subcommittee meeting was held May 3 and 4, 2001 with breakout working group sessions on Biomakers of Vasculitis and Cardiotoxicity. Next steps and management plans for this Subcommittee will be discussed.

Risk Based Chemistry Review Proposal Update

This proposal was introduced to ACPS at the November 2000 meeting. An AAPS workshop on this proposal was held June 12 and 13 to obtain industry input. An update on our internal efforts along with a summary of input received during the AAPS workshop will be presented.

Optimal Applications of In-line Process Controls in Pharmaceutical Production

This is a new topic area for discussion at the ACPS. Our initial thoughts on how FDA may facilitate introduction of "in-line" or "at-line" process controls in pharmaceutical manufacturing operations will be presented. The presentations will focus on challenges and opportunities of modern in-process controls.

Microbiology: New Technology Applications

Similar to the previous topic, this also is a new topic for discussion and will focus on issues related to introduction of new technology for microbial testing and evaluation. The focus of this discussion will be on the scientific basis for establishment of acceptance limits for microbiological tests that use newly developed technologies that do not rely on colony counts, and their application as process controls and product release criteria.

July 20 Sessions

Clinical Pharmacology

The need for clinically meaningful information in product labels for the appropriate use of drugs in pregnancy, breastfeeding women, and children, have led to several initiatives in FDA. A guidance document is being considered for lactation studies. An important objective of this effort is to provide a scientific framework for non-clinical and clinical studies for assessing the extent of drug transfer into breast milk, and when possible, drug exposure in the nursing infant. Issues for discussion at the ACPS meeting will focus on optimal methods to determine drug transfer into breast milk and interpretation of data.

Complex Drug Substances - Liposome Drug Products

There is a growing interest in the development of liposomal drug delivery systems and a number of such products have been approved. This discussion will focus on the challenges we face in defining pharmaceutical equivalence, bioavailability, and bioequivalence of these products.

Drafted 6/19/01 MW
Revised 6/19/01 HW